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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,515	02/07/2006	Andreas Katopodis	ON/4-33306A	1323
1095	7590	11/12/2008	EXAMINER	
NOVARTIS			SIMMONS, CHRIS E	
CORPORATE INTELLECTUAL PROPERTY			ART UNIT	PAPER NUMBER
ONE HEALTH PLAZA 104/3			1612	
EAST HANOVER, NJ 07936-1080				
		MAIL DATE	DELIVERY MODE	
		11/12/2008	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/567,515	<b>Applicant(s)</b> KATOPODIS, ANDREAS
	<b>Examiner</b> CHRIS E. SIMMONS	<b>Art Unit</b> 1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 25 July 2008.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 20 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

## DETAILED ACTION

Applicants' arguments, filed 07/25/2008, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Obviousness Rejection***

Claim 20 was rejected under 35 USC 103(a) as being unpatentable over Skov et al. in view of Catley et al. ***This rejection is maintained.***

Applicant argues that the histone deacetylase inhibitor taught in the Skov et al. reference, FR901228, is chemically and structurally different from the instantly claimed compound, LBH 589. Further alleging that since one skilled in the art would not conclude that the compounds that are structurally and chemically different would be expected to behave similarly, one would not find it obvious to combine the references.

The examiner does not find applicant's arguments to be persuasive. Even though the structures of the compounds are different, the references disclose them as having the same biochemical function as histone deacetylase inhibitors. This disclosure along with the additional disclosure in Skov et al. that histone deacetylase inhibitors are immunosuppressors that are useful in the therapeutic intervention against autoimmune diseases and allograft rejection (title, abstract) is believed to provide a *prima facie* case

of obviousness as outlined in the prior office action submitted on 02/04/2008. Examiner refers applicant to Daiichi Sankyo v. Apotex, 84 USPQ 1285 (Fed. Cir. 2007), where the court held that it would have been obvious to one of ordinary skill in the art to substitute ofloxacin for ciprofloxacin in the treatment of othopathy with a predictable expectation of successful treatment due to the compounds' functional similarities (both belong to the common class of gyrase inhibitors).

Examiner also refers applicant to KSR v. Teleflex, which now permits reasonable inferences as a basis for obviousness. Certainly the skilled artisan would be able to "reasonably infer" from the fact that the claimed compounds are histone deacetylase inhibitors that would be useful for the various purposes for which such inhibitors are typically used.

Claim 20 was rejected under 35 USC 103(a) as being unpatentable over WO 02/022577 in view of Skov et al. ***This rejection is maintained.***

Applicant's arguments are not found to be persuasive. These arguments are not persuasive because there is no difference between the structures of the WO reference and the elected compound of the instant claims. The WO reference teaches the exact same compound.

No claims are allowed.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRIS E. SIMMONS whose telephone number is (571)272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Chris E Simmons/  
Examiner, Art Unit 1612

*/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612*